

### REMARKS

This document is filed in reply to the Office Action dated November 18, 2003 ("Office Action").

Applicants have amended the specification to correct two typographical errors. Support for the amino acid sequence of "KTSIP" in SMEZ-2 can be found in, e.g., Figure 2, positions 120-124 of SEQ ID NO: 2.<sup>1</sup> Support for "[active at less than] 0.1 fg/ml" can be found in, e.g., Figure 7.<sup>2</sup> Applicants have narrowed claims 1 and 2 to specify that SMEZ-2 or its functionally equivalent variant contains an amino acid sequence of KTSIP.<sup>3</sup> At the Examiner's request, Applicants have also amended claims 1, 2, 14, and 31 to promote clarity and rectify informality. Support for "purified" now recited in claims 1, 2, and 31 can be found at, e.g., page 16, line 1 of the specification, and support for the amino acid sequence of "KTSIP" now recited in claims 1 and 2 has been discussed. No new matter has been introduced.

Claims 1-31 are pending. Claims 3-13 and 15-30, drawn to non-elected inventions, have been withdrawn. Claims 1, 2, 14, and 31 have been examined. Reconsideration of this application is requested in view of the following remarks:

#### Objection to Claim 14

The Examiner has objected to claim 14 for being informal. See the Office Action, page 2, lines 14-15. More specifically, the Examiner pointed out that a period was missing. Applicants have amended this claim to add the missing period.

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<sup>1</sup> To further support that KTSIP is the correct sequence, Applicants have submitted (1) a copy of SMEZ-2 polypeptide sequence deposited in GenBank (Accession No.: AAD52087, attached hereto as "Exhibit A") and (2) a copy of an article by Applicants' group (Proft et al., J. Exp. Med. 2000, V191, p1765-1776, attached hereto as "Exhibit B"). AAD52087 discloses the full-length SMEZ sequence. Table IV in Proft et al, discloses a part of the SMEZ sequence. Both sequences show that SMEZ contains KTSIP at positions 96-100. Since these two sequences are those of a mature SMEZ2 polypeptide, whose amino 24-residue leader sequence is degraded, the residues at positions 96-100 of this mature sequence correspond to positions 120-124 of SEQ ID NO: 2 disclosed in this application.

<sup>2</sup> Figure 7 is a diagram showing that four superantigens stimulated T cell proliferation. It clearly indicates that SMEZ-2 is active at less than  $10^{-7}$  ng/ml, i.e., at 0.1 fg/ml.

<sup>3</sup> Unlike SMEZ-2, some variants of SMEZ-2 do not contain KTSIP. To move this case toward allowance, Applicants have narrowed the scopes of claims 1 and 2 to exclude these KTSIP-free variants. Of note, to promote clarity, Applicants have recited in these two claims "SMEZ-2 ... contains an amino acid sequence of KTSIP."

Rejection under 35 U.S.C. § 101

The Examiner rejected claims 1, 2, and 31 as being directed to non-statutory subject matter. See page 3, lines 1-11 of the Office Action. At the Examiner's suggestion, Applicants have recited the word "purified" in all three claims and submit that the amendment has overcome the rejection.

Rejection under 35 U.S.C. § 102(b)

The Examiner rejected claims 1, 2, and 31 as being anticipated by Kamezawa et al. ("Kamezawa"). According to the Examiner, "Kamezawa discloses an SMEZ ... superantigen ... that appears to have the same functions ... as set forth by Applicants." See the Office Action, page 3, line 12 through page 4, line 2. As such, he concluded that "[i]t would appear that the superantigen taught in Kamezawa is a functionally equivalent variant of ... SEQ ID NO: 2." See the Office Action, page 5, lines 6-8.

Applicants have amended claims 1 and 2. Claim 1, as amended, covers a superantigen selected from SMEZ-2, SPE-G, SPE-H, and SPE-J, or their functionally equivalent variants. Amended claim 2 covers a superantigen SMEZ-2 that has the amino acid sequence of SEQ ID NO: 2, or its functionally equivalent variant. In both claims, the functionally equivalent variants of SEQ ID NO: 2 must have the sequence of KTSIP. In contrast, the SMEZ superantigen taught in Kamezawa does not contain this sequence. Clearly, the Kamezawa SMEZ superantigen is not a functionally equivalent variant of SMEZ-2 as recited in claims 1 and 2. Thus, claims 1 and 2, as amended, are not anticipated by Kamezawa. Neither is claim 31, which depends from claim 2.

The Examiner appeared to also reject claims 1, 2, and 31 as being obvious over Kamezawa on the same ground described above. See the Office Action, page 5, lines 10-15. Applicants respectfully traverse. As set forth above, Kamezawa does not teach a SMEZ superantigen containing the sequence of KTSIP. Neither does it suggest any SMEZ superantigen variant containing this sequence. Therefore, it does not render the three claims at issue obvious.

Applicant : John D. Fraser, et al.  
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CONCLUSION

For the above remarks, Applicants submit that the grounds for rejection asserted by the Examiner have been overcome, and the claims, as pending, define subject matter that is useful, novel, and non-obvious. On this basis, it is submitted that allowance of this application is proper, and early favorable action is solicited.

Enclosed is a \$950 check for the required fee for a Petition for Three Month Extension of Time. Please apply any other charges to deposit account 06-1050, referencing attorney docket 12669-003US1.

Respectfully submitted,

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